

## REMARKS

This is in response to the Office Action mailed on May 18, 2009, in which claims 39-51 were rejected under 35 U.S.C. § 101; claims 39-41 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Pub. No. 2002/0022776 (*Bardy*); claims 42 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of U.S. Patent No. 6,250,309 (*Krichen*); claims 44-48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of U.S. Patent Pub. No. 2004/0243545 (*Boone*); claims 49 and 50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Boone*, and further in view of U.S. Patent Pub. No. 2002/0077865 (*Sullivan*); and claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of U.S. Patent Pub. No. 2001/0053984 (*Joyce*). With this Amendment, claims 1-38 are canceled, with the applicant reserving the right to pursue the canceled claims in one or more divisional applications. In addition, claim 39 is amended and claims 52-62 are added. Claims 39-62 are pending in the present application.

### Examiner Interview

On August 26, 2009, a telephonic interview was conducted between Examiner Lena Najarian, and the undersigned to discuss the standing rejections under 35 U.S.C. § 102. The undersigned thanks Examiner Najarian for the courtesy of this interview. During the interview, the undersigned presented proposed amendments to independent claim 39 as well as proposed new claims. No agreement was reached.

### Claim Rejections – 35 U.S.C. § 101

Claims 39-51 stand rejected under 35 U.S.C. 101, as being directed to non-statutory subject matter. As noted in the recent Federal Circuit decision, *In re Bilski*, a claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008). With this Amendment, claim 39 is amended to recite that a data set is received from an implantable medical device via a data input device, and that the

analyzing and comparing steps are performed with a data processor. Support for these amendment are found in the original specification at, for example, paragraphs 0052 and 0122-0124. Accordingly, the elements of the process are tied to a particular machine or apparatus in accordance with the test for patentable subject matter set forth in *Bilski*. Consequently, because the method of claim 39 is directed to patentable subject matter, it is respectfully requested that the rejection of claims 39-51 under 35 U.S.C. §101 be withdrawn.

### **Claim Rejections – 35 U.S.C. § 102**

Claims 39-41 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Bardy*. With this Amendment, claim 39 is amended. Amended claim 39 recites a method for automatically validating medical data received via a communication network. A data set is received from an implantable medical device, and the data set is analyzed to determine implantable medical device configuration parameters. The implantable medical device configuration parameters are then compared to predefined clinical trial configuration parameters to determine whether the implantable medical device configuration parameters are configured properly. Support for the amendments to claim 39 may be found, for example, at paragraph 0124 of the original specification.

*Bardy* does not teach all limitations of amended claim 39. In order for a claim to be anticipated, each and every element of the claim must be described in a single prior art reference. MPEP § 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *Bardy* teaches a system for the automated collection and analysis of patient information retrieved from a medical device. A patient status indicator is determined based on the patient's collected data sets and stored data sets from other patients. *Bardy*, ¶ 0011. The purpose of collecting data sets is "to make a determination of general patient wellness based on comparisons and heuristic trends analyses of the measures." *Bardy*, ¶ 0053. However, nothing in *Bardy* teaches or suggests the use of data sets to determine implantable medical device configuration parameters, which are compared to predefined clinical trial configuration parameters to determine whether the implantable medical device configuration parameters are configured properly as required by

claim 39. Therefore, it is respectfully requested that the rejection of claims 39-41 under 35 U.S.C. § 102(b) be withdrawn.

### **Claim Rejections – 35 U.S.C. § 103**

Claims 42 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Krichen*, claims 44-48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Boone*, claims 49 and 50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Boone* and further in view of *Sullivan*, and claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Joyce*. None of the cited references cure the deficiencies discussed above with respect to claim 39. In addition, claims 42-51 depend from allowable claim 39, and thus are allowable therewith. Furthermore, it is respectfully submitted that the combinations of features recited in claims 42-51 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

### **New Claims**

New claims 52-62 are added with this amendment. Support for new claims 52-62 are found in the original specification at, for example, paragraphs 0122-0124. Consideration and allowance of new claims 52-62 are respectfully requested

### **CONCLUSION**

For the reasons explained above, all pending claims are now in condition for allowance. Accordingly, the applicant respectfully requests that the Office issue a Notice of Allowance.

Any amendments to the claims are made to expedite prosecution of this application, without acquiescing to the Office's rejections or characterizations of the claims or references in the Office Action. Even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references.

The Applicant has made a good faith effort to respond to all rejections set forth in the Office Action and to place the pending claims in condition for immediate allowance. If it would be helpful, the Examiner is invited to contact the undersigned at the number listed below to facilitate prosecution of this application.

Respectfully submitted,

FAEGRE & BENSON LLP

Dated: September 17, 2009

By: /Paul G. Koziol/  
Paul G. Koziol  
Reg. No. 58,515  
612/766.8965  
Customer No.: 42074